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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,610	08/15/2005	Nobuo Tomioka	P25921	8492

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EXAMINER	
WHALEY, PABLO S	

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
03/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/506,610	TOMIOKA ET AL.	
	Examiner	Art Unit	
	PABLO WHALEY	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *3-5,9,18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-8,10-17 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/11/2010; 12/02/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Applicant's election with traverse of Species A drawn to species of information on bio-events (claims 2 and 14), and Species B drawn to species of analyzed information that includes quantitative or qualitative changes of biomolecules (claim 17) in the reply filed on 10/30/2009 is acknowledged. Applicant's arguments that there does not appear to be a serious search burden given the nature of the species have been fully considered but are not persuasive for the reasons set forth in the Office action mailed 10/05/2009. More specifically, the disclosed species are all non-overlapping subject matter that is separately classified and published in the art. Claims 3, 4, 5, 9, 18, and 19 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

Claims 1-25 are pending. Claims 1, 2, 6-8, 10-17, and 20-25 are under consideration.

Information Disclosure Statement

The information disclosure statement filed 02/11/2010 has been considered in full.

The information disclosure statement filed 12/02/2009 has been considered in full.

Objections

The objection of claim 1 is withdrawn in view of applicant's amendments filed 12/02/2009.

Withdrawn Rejections

The rejection of claims 6-8 and 12-20 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendments filed 12/02/2009.

The rejection of claims 1-20 under 35 U.S.C. 101 is withdrawn in view of applicant's amendments filed 12/02/2009.

The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Winslow is withdrawn in view of applicant's amendments filed 12/02/2009.

The rejection of claims 1-20 under 35 U.S.C. 103(a) as being unpatentable over Winslow and Itai is withdrawn in view of applicant's amendments filed 12/02/2009.

Claim rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

This rejection is necessitated by amendment.

Claims 20-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-23 provide for the use of the method of claim 1, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

This rejection is necessitated by amendment.

Claims 24-25 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

Claim 24 is drawn to a program for carrying out the method of claim 1. However, the program as claimed is not embodied on a computer and does not comprise any limitations or instructions such that it is interpreted as a physical product or a method. For these reasons, the instant claim reads on a program, per se, and is not statutory.

Claim 25 is drawn to computer readable medium which stores the program for carrying out the method of claim 1. The computer readable medium is not defined by the specification to be a physical object, therefore the claims are not necessarily directed to a physical product. For these reasons, the claim is not statutory.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 10, 11, 15, 16, and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winslow et al. (1999; IDS filed 05/13/2008).

The instant invention is drawn to a method of generating and displaying a molecule function network by a computer comprising: using a database comprising information on biomolecule pairs and information on bio- events which correlates a bio-event to a biomolecule or a biomolecule pair which

causes the bio- event, the computer searches information on biomolecule pairs for generating information on contiguous linkages of molecules wherein the number of the linkages is within a designated number, starting the search from a biomolecule designated by a user from biomolecules contained in a first molecule network representing linkages of molecules; based on the information on biomolecule pairs obtained by the search, the computer generates and displays a second molecule network comprising the first molecule network and information on contiguous linkages of molecules which starts from the biomolecule designated by the user; and the computer further searches and displays information on bio-events correlated to biomolecules or biomolecule pairs contained in the second molecule network. The instant invention is also drawn to a method of presuming a mechanism of action of a drug molecule using the method of claim 1; a method of presuming a target biomolecule for drug development using the method of claim 1; a method of presuming a target biomolecule of a drug molecule using the method of claim 1; a program for carrying out the method of claim 1; and a computer readable medium storing the program for carrying out the method of claim 1.

Winslow teaches a method, system, and database for quantitative understanding of biological processes [Abstract and p.4]. In particular, the system comprises biochemical databases storing genetic and biochemical reaction network data for the hierarchical construction of computational models of these networks from their underlying components [p.9], which is a teaching for at least two molecular networks. The biological information in the data is used to generate a data structure that is associated hierarchical information related to cellular function [Abstract and Fig. 6]. In one embodiment, the data structure includes a gene regulatory network comprising proteins, polymerase complexes, and promoters [p.14 and Fig. 6]. Information is displayed by way of graphical user interface for viewing information, linking attributes, and searching the database [Abstract, p.5, ¶2, p.9, Fig. 5, Fig. 8]. A user can retrieve any of the data associated with or generated by the data structures and their linked lists [p.15, ¶2]. Winslow shows the storage of data that effects the expression of proteins, such as the presence of disease

[p.12, last ¶], which shows a correlation of a protein to a bio-event. The method can numerically screen compounds for functional effects, and analyze information such the rate of change of reaction concentrations [p.7, ¶2 and p.18], which is interpreted as analyzing information on quantitative changes of biomolecules. The method generates attribute lists and provides relationships between data items that include history and initial conditions [p. 12, p.14, p.32, Table]. The method uses computer implemented tools for analyzing genetic processes and linking this information to health and disease [p.4, p.7, ¶2, p.12, ¶3]. The method allows for the analysis of protein data and can be linked to existing genetic, protein, and structural databases [p.3, p.12].. The method can be used to identify new drug targets and drug screening [Abstract], which is interpreted as presuming a mechanism of action of a drug molecule as claimed.

Winslow does not specifically recite the term "biomolecule pairs", as in claim 1. However, this limitation would have been obvious to one of ordinary skill in the art at the time of the instant invention since the method of Winslow teaches databases comprising information for proteins, polymerase complexes, and promoters [p.14 and Fig. 6], which implicitly shows biomolecule pairs as claimed.

Winslow does not specifically teach a computer that generates and displays a second molecule network comprising the first molecule network and information on contiguous linkages of molecules which starts from the biomolecule designated by the user, as in claims 1 and 16. However, this limitation would have been obvious to one of ordinary skill in the art at the time of the instant invention since the method of Winslow shows generating "first level" binary data structures [p.13], pathway data structures based on a composition of binary data structures [p.14], and database elements arranged in hierarchical format [p.12], which implicitly shows a second molecule network comprising a first molecule network and information on contiguous linkages of molecules which starts from the biomolecule designated by the user, as claimed.

Claims 1, 2, 6, 7, 10-12, 14-17, 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winslow et al. (1999; IDS filed 05/13/2008), in view of Itai et al. (1999; IDS filed 05/13/2008), in view of Kanehisa et al. (Nucleic Acids Research, 2000, Vol. 28, No. 1, p.27-30), and in view of Takai-Igarashi et al. (In Silico Biology, 1999, p.129-146; IDS filed 10/25/2005).

Winslow makes obvious a method of generating and displaying a molecule network, as set forth above.

Winslow does not teach a database storing information on exaltation, increase, suppression, or decrease of a bio-event in response to quantitative or qualitative change of the biomolecule which causes the bioevent, as in claim 2.

Winslow does not teach a database storing information on directionality of relation between two molecules constituting a biomolecule pair, and searching based on directionality, as in claim 6.

Winslow does not teach displaying the second molecule network with information on directionality of relation of the biomolecule pairs contained in the second molecule network, as in claim 7.

Winslow does not teach a database storing information on directionality of relation between two molecules constituting a biomolecule pair, and scoring molecule networks based in information directionality, as in claim 12.

Takai-Igarashi teaches a pathway finding system for the cell signaling networks database. All the reactions are initially described as pairs of molecules with an explicit direction [p.130, last ¶]. One molecule must be the signal transmitter and the other must be the receiver. Graphic examples of reactions are presented wherein arrows are used as an indication of directionality of the reaction [See at least Fig. 3, 4, and 5]. Takai-Igarashi stores a plurality of different attributes from reaction pathways in a database and correlate this parameters to specific molecules, which can be indicated as activated or inactivated [See at

least p.136 and p.145], which is interpreted as an increase or decrease of a bioevent. The pathway generation method determines the maximum number of connecting steps [See at least p.141 and Fig. 6], which is interpreted as scoring of directional pathways. The database can be queried with user-defined search parameters [Fig. 6].

Kanehisa teaches a system for displaying molecular interactions [Fig. 1]. In particular, the system includes regulatory, metabolic, and genomic pathway information [Fig. 2], wherein interactions gene products can be directly correlated with genes in the genome for example. The motivation would have been to automatically expand a collection of manually drawn pathway diagrams [p.30, Col. 1].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Winslow by storing information on exaltation, increase, suppression, or decrease of a bio-event in response to quantitative or qualitative change of the biomolecule which causes the bioevent, as in claim 2, since Takai-Igarashi stores a plurality of different attributes from reaction pathways in a database and correlate this parameters to specific molecules, which can be indicated as activated or inactivated [See at least p.136 and p.145], and since Kanehisa displays molecular interactions wherein gene products can be directly correlated with genes in the genome, as set forth above. The motivation would have been to automatically expand a collection of manually drawn pathway diagrams, as suggested by Kanehisa [p.30, Col. 1].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Winslow by storing information on directionality of relation between two molecules constituting a biomolecule pair, and searching based on directionality, as in claim 6, or by displaying the second molecule network with information on directionality of relation of the biomolecule pairs contained in the second molecule network, as in claim 7, since Takai-Igarashi shows reaction networks between a plurality of pairs of molecules using arrows to indicate directionality, as set forth

above. The motivation would have been to automatically find relationships in large collections of cell signaling data, as suggested by Takai-Igarashi [Abstract].

Claims 1, 2, 6-8, 10-17, and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winslow et al. (1999; IDS filed 05/13/2008), in view of Itai et al. (1999; IDS filed 05/13/2008), in view of Kanehisa et al. (Nucleic Acids Research, 2000, Vol. 28, No. 1, p.27-30), in view of Takai-Igarashi et al. (In Silico Biology, 1999, p.129-146; IDS filed 10/25/2005), and in view of Hogue et al. (WO/00/48092; Published 17 August 2000; IDS filed 10/25/2005).

Winslow, Kanehisa, and Takai-Igarashi make obvious a method of generating and displaying a molecule network, as in claims 1, 2, 6, 7, 10-12, 14-17, and 20-25, above.

Winslow, Kanehisa, and Takai-Igarashi do not teach a method wherein: the database further comprises one or more data items selected from a relation code representing a relation between two molecules constituting a biomolecule pair, a relation-function code representing a phenomenon or a change accompanied by direct binding of two molecules constituting a biomolecule pair, a reliability code indicating reliability level of information on a biomolecule pair or an experimental method whereupon information on a biomolecule pair is proved, information on an originating region where a biomolecule is originated, information on an existing region where a biomolecule is stored after its generation, and information on an acting region where a biomolecule causes a bio-event; and the computer carries out the search of information on biomolecule pairs based on one or more data items selected from the data items contained in the database, wherein the one or more data items used for the search are designated by the user, as in claims 8 and 13.

Hogue teaches a system for electronically managing biomolecular interactions. In particular, a plurality of different identifier codes are used for labeling the molecular data stored in the database [See

p. 9-12]. For example, identifiers are described labeling interactions, indicating the type of molecules, indicating the presence or absence of cell stages, indicating structural information, identifying the chemical origin of the molecule, identifying experimental conditions, etc. [See p. 9-13].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method made obvious by Winslow, Kanehisa, and Takai-Igarashi using relation code representing a relation between two molecules constituting a biomolecule pair, a relation-function code representing a phenomenon or a change accompanied by direct binding of two molecules constituting a biomolecule pair, a reliability code indicating reliability level of information on a biomolecule pair or an experimental method whereupon information on a biomolecule pair is proved, information on an originating region where a biomolecule is originated, information on an existing region where a biomolecule is stored after its generation, and information on an acting region where a biomolecule causes a bio-event; and the computer carries out the search of information on biomolecule pairs based on one or more data items selected from the data items contained in the database, wherein the one or more data items used for the search are designated by the user, as in claims 8 and 13, since Winslow teaches a plurality of attributes for associating and searching data in a database [p.9, 15, and 32-33], and since Hogue explicitly teaches different identifier codes for labeling molecular interactions, indicating the type of molecules, indicating the presence or absence of cell stages, indicating structural information, identifying the chemical origin of the molecule, and identifying experimental conditions, as set forth above, which reasonably suggests relation codes, relation function codes, and reliability codes, as claimed. The motivation would have been to decrease search time by filtering data according to user-defined beneficial for assigning importance to effectively determine biological function [0019].

Response to Arguments

Applicant's arguments/remarks submitted in the amendment filed 05/18/2009 have been entered and fully considered but are moot in view of the new ground of rejections.

Notice of Change to Docketing of Requests for Continued Examination

Applicant is reminded of the change in docketing of Requests for Continued Examination set forth in the online OG Notice of 10 November 2009 (*1348 OG 254*; http://www.uspto.gov/web/offices/com/sol/og/2009/week45/TOC.htm#ref14).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached between 12pm-8pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner

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